

Office of Regulatory Policy Program Description

Office Description: The Office of Regulatory Policy provides Center oversight and leadership in the development of regulations, policies, and procedures that affect the drug approval process, and in the development of new legislation. It also responds to any requests for disclosure of information under the Freedom of Information Act and other statutes and affirmatively discloses documents that the Agency wants to disclose.

Goals: The purpose of this rotation is to familiarize the student with the role of the Food and Drug Administration (FDA) in the regulation of human drug products, with special emphasis on rulemaking and the role of citizen petitions.

Learning Objectives: Upon completion of this rotation, the student will be able to:

1. Describe FDA's role in the development, approval, and postmarket surveillance of human drug products.
2. Discuss the drug review and approval process.
3. Describe key statutes that affect human drug products.
4. Discuss notice and comment rulemaking.
5. Describe the official means of communicating with regulated industry and the public.
6. Distinguish between OTC drug products that are marketed under a new drug application (NDA) versus the monograph system.
7. Utilize FDA and external resources such as CDER guidance documents, Federal Register, DailyMed, Drugs@FDA, Electronic Orange Book, www.Regulations.gov, and the Unified Agenda.
8. Discuss the differences and similarities of laws, regulations, and guidance documents governing human drug products.
9. Describe the process of responding to citizen petitions and the role citizen petitions can play in drug regulation.

Student Requirements:

1. Give a 10-15 minute presentation.
2. Perform special projects (e.g., collect and organize drug information) as requested by regulatory counsels.
3. Attend FDA's Pharmacy Student Experiential Program lectures.
4. Fulfill required hours.